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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,317	08/20/2004	Tina Rademacher	RO0861US(#90568)	5171

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,317	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on ____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 27-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 27-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *all*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 8-13, 15-31 and 33-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-13, 15 and 16 of copending Application No. 10/468230 ('230), in view of US 2006/0057207 ('207). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '230 patent application claims a flat-shaped mucoadhesive medicinal preparation for administering active substances in veterinary or human medicine, containing at least one active substance, characterized in that the preparation is a mucoadhesive matrix disintegratable in aqueous media, which matrix contains at least one matrix-forming polymer and wherein at least one

active substance is dissolved or dispersed, and that the said preparation disintegrates or erodes within 15 minutes after introduction in an aqueous medium or in body fluids (claims 1, 2, 13 and 15). Density and thickness of the mucoadhesive preparation are found in claims 3 and 4. The preparation's shapes are found in claim 10. Solid foam is found in claim 11. Additional additives are found in claims 7-9. Disintegration of the preparation within 60 second is found in claim 6. Matrix-forming polymer is found in claim 12. Process for administering the preparation is found in claim 16. The only deficiency of the '230 application is the teaching of carbon dioxide-forming substance.

However, publication '207 teaches a fast-disintegrating dosage form comprising an effervescent disintegration agent (saliva activating agent) such as sodium carbonate (paragraph 0048; claims 7 and 12). The amount of effervescent disintegration agent is from about 0.05% to about 30% (paragraph 0061). Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage form of the '230 application to include the disintegrating agent in view of the teaching of the '207 publication, because the '207 publication teaches using sodium carbonate as an effervescent disintegration agent to stimulate saliva, thereby providing additional water to aid in further effervescence and disintegration of the dosage form (paragraph 0046).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 8-13, 15-31 and 33-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2,

4-9, 13, 15-21, 23, 42-48, 52-82 of copending Application No. 10/517093 ('093), in view of US 2007/0122455 ('455). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '093 patent application claims a film-shaped preparation disintegratable in aqueous media comprising at least one water-soluble polymer, one gas-forming component such as carbonates (claims 1, 2, 4, 7-9 and 15). Disintegration time is found in claims 13, 53 and 54. Film thickness in found for example in claim 45. The only deficiency of the '093 application is the teaching of a specific water-soluble polymer.

However, publication '455 teaches a rapid-dissolved dosage form comprising film-forming polymer includes HPMC, and ethyl cellulose (abstract; and paragraph 0063). Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage form of the '230 application to include the film-forming polymer in view of the teaching of the '455 publication, because the '455 publication teaches film-forming polymers well known for use in rapid-dissolved dosage such as an edible film.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33, 34 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 34 recite the limitation "thickness" in line 2. It appears that this limitation is typographical error. However, there is insufficient antecedent basis for this limitation in the claim. Claims 33 and 34 depend in claim 15, while claim 15 recites "density".

This claim is rejected because it is not clear whether applicant intend to claim a process of making the preparation or a process of administering the preparation. In the first 4 lines, the claim recites "A method for administering a pharmaceutical preparation containing an active substance...comprising the steps of". However, in the next 20 lines, the claim appears to recite a process for preparing the film. Further, the process appears to be incomplete because adding all the ingredients without any further steps does not make a film. Accordingly, for examining purpose, the claim is interpreted as a method for administering a pharmaceutical preparation by applying said preparation to the surface of oral mucosa for disintegration in the aqueous media (see the first four lines and last two lines of the claim). This is because the patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-12, 16, 17, 20, 21, 29-31, 35, 36 and 39-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Falkenhausen et al. WO 02/02085 A2 (using US Publication 2004/0028732).

Falkenhausen teaches a rapidly disintegrating sheet or wafer dosage form having thickness of between 0.1-5 mm, the dosage form comprising matrix-forming polymers, active ingredients, and a carbon dioxide gas forming agent (paragraphs 0006, 0036 and claim 11). Polymers include cellulosic polymers, and water-soluble polysaccharide (abstract; paragraphs 0017-0020). The dosage form further comprises eucalyptus oil, peppermint oil, flavor, sweetener, other additives, and foams such as propylene glycol (paragraphs 0023-0030). The dosage form disintegrates in the oral cavity in the range from 10-30 second (paragraph 0009).

Claims 1-3, 5-12, 15-21, 29-31 and 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ziegler et al. US 2006/0057207 A1.

Ziegler discloses a fast disintegrating film or wafer comprising: an active agent, film-forming polymers, effervescent disintegrant (gas-forming agent), and filler (paragraph 0074). Film-forming polymers are disclosed in paragraph 0076. The film-forming polymers are added in an amount that falls within the claimed range, *e.g.*, 0.01-99% (paragraph 0076). Effervescent disintegrant includes sodium carbonate (paragraph 0048). The film further comprises water, additional film-forming agent, plasticizing agent, flavoring, saliva stimulating agents, cooling agent, surfactant, stabilizing agent, emulsifying agent, thickening agents, binding agent, coloring agent, sweetening agent, fragrance, and the like (paragraphs 0077-0088). Ziegler further discloses the film has a thickness that falls within the claimed range, *e.g.*, 30 μm to 300 μm (paragraph 0074). Ziegler also discloses the film disintegrates in a patient's oral cavity in less than one minute (paragraph 0009).

It is noted that Ziegler does not explicitly teach the claimed properties such as the density. However, the density is inherent because Ziegler teaches the use of the same polymer, and the same carbon dioxide forming agent to obtain the same wafer composition having the claimed disintegrating time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 15-21, 27-31 and 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al. US 2006/0057207, in view of Pather et al. US 2003/0091629.

Ziegler is relied upon for the reason stated above. Ziegler does not specifically teach the claimed amount of the gas-forming agent. However, Ziegler teaches the use of saliva stimulating agent in an amount that falls within the claimed range, *e.g.,* about 0.01% to about 12% (paragraphs 0061 and 0078). Most importantly, Ziegler discloses the use of sodium carbonate as an effervescent disintegration agent to stimulate saliva production, thereby providing additional water to aid in further effervescence and disintegration (paragraph 0046). To be more specific, Pather teaches an effervescing sublingual buccal dosage form comprising a drug, an additive, and an effervescent in an amount of about 5% to about 95% (abstract; and paragraph 0014). Pather further teaches effervescent includes sodium carbonate, and potassium carbonate (paragraph 0015).

Thus, it would have been obvious to one of ordinary skill in the art to modify the fast disintegrating dosage of Ziegler to include the carbonates in an amount in view of the teaching of Pather to obtain the claimed invention. This is because Pather teaches the use of effervescent in such an amount to influence the permeability of the medicament across the buccal, sublingual, and gingival mucosa (paragraphs 0008 and 0009), because Ziegler teaches the use of sodium carbonate in the dosage form, and because Ziegler teaches the desirability to obtain a fast disintegrating dosage form useful for buccal and sublingual delivery.

Claims 1-12, 16, 17, 19-21, 27-31, 35, 36 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falkenhausen et al. WO 02/02085 A2 (using US Publication 2004/0028732), in view of Pather et al. US 2003/0091629.

Falkenhausen is relied upon for the reason disclosed in the 102(a) rejection. Falkenhausen does not explicitly teach the claimed carbon dioxide forming substance.

Pather teaches an effervescing sublingual buccal dosage form comprising a drug, an additive, and an effervescent in an amount of about 5% to about 95% (abstract; and paragraph 0014). Pather further teaches effervescent includes sodium carbonate, and potassium carbonate (paragraph 0015).

Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage of Falkenhausen to include the carbon dioxide forming substance such as sodium carbonate in an amount in view of the teaching of Pather to obtain the claimed invention. This is because Pather teaches the use of effervescent in such an amount to influence the permeability of the medicament across the buccal, sublingual, and gingival mucosa (paragraphs 0008 and 0009), because Pather teaches the use of sodium carbonate to evolve gas such as carbon dioxide gas (paragraphs 0015-0016), and because Falkenhausen teaches the desirability of using carbon dioxide gas forming substance.

Falkenhausen further does not teach the amount of water-soluble polymer. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not

inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The examiner is unable to determine any unexpected result over the claimed amount of polymer because Falkenhausen teaches the use of the same matrix-forming polymer to obtain a rapidly disintegrating film that has the same disintegration time, *i.e.*, 10-30 second (ID). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select an amount of matrix-forming polymer that falls within the claimed range, because Falkenhausen the desirability to use the same matrix-forming polymer to obtain the same film shape dosage form having the same disintegrating time.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al. or Falkenhausen et al., in view of Myers et al. US 2007/0122455.

Ziegler and Falkenhausen are relied upon for the reasons stated above. The references do not teach ethyl cellulose as firm-forming polymer.

Myers teaches a uniform film for rapid-dissolve dosage form comprising ethyl cellulose as a matrix-forming polymer (paragraph 0063).

Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage of Ziegler or Falkenhausen using ethyl cellulose as a film-forming polymer in view of the teaching of Myers, this is because Myers teaches using ethyl cellulose in rapid-dissolve film-shaped dosage form is well known in the art, and this is because Ziegler and Falkenhausen teach the desirability for using cellulosic film-forming polymers.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al., in view of Tapolsky et al. US 5,800,832.

Ziegler is relied upon for the reasons stated above. The reference does not expressly teach the film layers as claimed in claims 13 and 14.

Tapolsky teaches a water-soluble, bioerodable delivery device comprising an adhesive layer and a non-adhesive backing layer (abstract). The two layers have different dissolution rate (permeability) (column 5, lines 34-36). Thus, it would have been obvious to one of ordinary skill in the art to modify the delivery thin film of Ziegler to contain the mucoadhesive bioerodable film in view of the teaching of Tapolsky, because Tapolsky teaches a mucoadhesive bioerodable film provides adhesive to mucosal surface with minimal discomfort and ease of use (column 4, lines 47-50), because Tapolsky teaches using mucoadhesive to maintain the delivery device at the site of treatment (column 1, lines 13-21), and because Ziegler teaches the thin film delivery system includes multi-layer system (paragraph 0074).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Murakami et al., Misra et al., and Zoumut are cited as of interest for the teachings of quickly disintegrable dosage forms.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SUSAN TRAN
PRIMARY EXAMINER

Art Unit 1615